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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,358	11/20/2006	Ashfaque Hossain	CRE-102.1 US (8492/96340)	5617

24628 7590 01/06/2010
Husch Blackwell Sanders, LLP
Husch Blackwell Sanders LLP Welsh & Katz
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER	
BABIC, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,358	HOSSAIN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. BABIC	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 9-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7, and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claim(s) 1-5, 7, and 9-14 are pending and under examination. The following Office Action is in response to Applicant's communication dated September 27, 2009.

Claim Rejections - 35 USC § 102 - Withdrawn

Applicant's claim amendments and supplemental remarks are sufficient to overcome the rejection of claim(s) 1, 3, and 5-14 over Mehra. Thus, the rejection has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (J Clin Microbiol. 2000 Dec;38(12):4326-31) in view of Chomczynski (U.S. 5,346,994), and in further view of Majumdar et al. (Biotechniques. 1991 Jul;11(1):94-101).

With regard to claims 1-3 and 8-14, Cook teaches methods of RNA isolation from biological specimens (pg. 4327, methods, col. 1, for example). Specifically, the reference teaches methods (pg. 4327, col. 1, RNA extraction from whole blood, for example) comprising: (a) contacting the biological specimen with an admixture of (i) a mono-phasic solution of phenol and guanidine isothiocyanate (pg. 4327, col. 1, RNA extraction from whole blood, 2nd solution, TRIZOL solution necessarily contains phenol and guanidine isothiocyanate, for example), and (ii) a lysis buffer under conditions and for a time appropriate to form a homogenate (pg. 4327, col. 1, RNA extraction from whole blood, 1st solution, CATRIMOX solution necessarily contains a dispersing agent, i.e. detergent, for example); (b) admixing the homogenate with a water-immiscible organic solvent under conditions and for a time appropriate to form an aqueous phase and an organic phase (pg. 4327, col. 1, RNA extraction from whole blood, RNA was extracted by manufacture's instructions, for example); (c) contacting the aqueous phase with a C_1-C_4 lower alcohol under conditions and for a time to form a precipitated RNA

(pg. 4327, col. 1, RNA extraction from whole blood, RNA was extracted by manufacture's instructions, for example); and (d) recovering the precipitated RNA (pg. 4327, col. 1, RNA extraction from whole blood, RNA was extracted by manufacture's instructions, for example).

With regard to the "admixture" of solutions (i) and (ii), Cook expressly teaches that the CATRIMOX-TRIZOL method was performed on some samples without the two DEPC water washes (pg. 4327, col. 1, RNA extraction from whole blood, for example). Thus within these methods, a CALTRIMOX residue was present in the reaction vessel during the addition of TRIZOL reagent.

With regard to the "manufacturer's instructions" referenced by Cook (pg. 4327, TRIZOL from Life Technologies, reference 5, for example), the Office believes it is understood that such instructions included the steps of: 1) forming aqueous/organic phases; and 2) RNA precipitation w/ isopropanol to isolate RNA from the TRIZOL homogenate, as such steps were considered standard in the art at the time of invention; however, in order to provide a clear understanding of the grounds of rejection, the Chomczynski reference is provided to demonstrate such method steps as standard methodology within RNA TRIZOL-based isolation at the time of invention (see Chomcynski; col. 5-6, Example 2, chloroform and isopropanol, for example).

With regard to the above claims, the CATRIMOX lysis buffer referenced by Cook does not appear to comprise a chelating agent (e.g. EDTA) as required by the claimed invention. Also, Cook does not teach RNA isolation from bacterium.

Majumdar provides a supportive disclosure that expressly teaches methods of bacterial RNA isolation that include an initial homogenization step that utilizes a lysis buffer comprising a dispersing agent (e.g. detergent) and a chelating agent (e.g. EDTA) (abstract; pg. 96-97, lysis of bacterial cells, TRITON-X100 and EDTA, for example). The reference expressly teaches EDTA as an essential reagent (pg. 99, col. 2), further highlighting that the simple extraction methods are useful for obtaining good yields from large and small samples (pg. 100, col. 3). It is submitted that referring to EDTA as an essential reagent would not have been surprising to one of ordinary skill in the art at the time of invention given that EDTA was commonly known as a metal complexing agent, free metal ion activity being undesirable within isolated RNA solutions.

With regard to claims 4, 5, and 7, Majumdar teaches mammalian and *C. vibrioforme* samples (pg. 96-97, for example).

Thus, in summary, it is first submitted that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to apply the RNA isolation methods of Cook to bacteria since Mehra recognized that detergents were appropriate lysis reagents for bacterial nucleic acid isolation methods.

Furthermore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to utilize steps (b) and (c) of the claimed method as demonstrated by Chomczynski in the methods of Cook since the prior art expressly demonstrates such steps as standard practice within TRIZOL-based isolation methods.

Furthermore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to include a chelating agent (e.g. EDTA) within the lysis

buffer of Cook since the prior art expressly demonstrates such a chemical as essential to providing good RNA yield. One of ordinary skill in the art would recognize the benefit of including such a chemical so as to form metal complexes thereby reducing free metal ion activity.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that application of one method to the extraction of RNA from whole blood does not suggest at a similar method could successfully be used for the extraction of RNA from bacterium. The examiner respectfully disagrees. First, as noted above, Mehra expressly teaches a detergent-based lysis procedure, i.e. application of a detergent (Triton) for the purpose of disrupting cellular structure. Thus, one of ordinary skill in the art would have expected catrimox, a detergent, to be an appropriate lysis reagent for bacterial nucleic acid isolation. Furthermore, as was well known in the art at the time of invention, Chomczynski teaches of the TRIZOL reagent that, "The guanidinium compound serves to protect the RNA and DNA components from degradation, and serves to maintain the phenol in solution in the aqueous solvent solution. The phenol serves to extract the proteins from the aqueous phase and inhibit the action of RNase and other contaminating enzymes which cause RNA degradation (col. 3)." Thus, one of ordinary skill in the art would have expected the TRIZOL reagent to be a beneficial additive to bacterial nucleic acid isolation.

Thus, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Examiner
Art Unit 1637
Technology Center 1600

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637